PATENT APPLICATION

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TISSUE DISTRACTION DEVICE

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TISSUE DISTRACTION DEVICE

REFERENCE TO RELATED APPLICATION

This application claims priority to co-pending provisional application No. 60/459,036, filed on March 31, 2003, in the name of the present inventors. The disclosure of this provisional application No. 60/459,036 is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention involves the field of surgery, and particularly to the field of orthopaedic surgery, surgical instruments and methods of using the same. The invention has particular application in distracting and supporting tissue surfaces, such as bone surfaces.

BACKGROUND OF THE INVENTION

A variety of physical conditions involve two tissue surfaces that, for treatment of the condition, need to be distracted from one another and then supported away from one another. Such distraction may be to gain exposure to select tissue structures, to apply a therapeutic pressure to select tissues, to return tissue structures to their anatomic position and form, or in some cases to deliver a drug or growth factor to alter, influence or deter further growth of select tissues. Depending on the condition being treated, the tissue surfaces may be opposed or contiguous and may be bone, skin, soft tissue, or a combination thereof. An optimal treatment method includes distracting and supporting the tissue surfaces simultaneously.

A minimally invasive distraction and support device would have significant application in orthopaedic surgical procedures, including acute and elective procedures to treat bone fractures and degenerative changes of the skeletal system and including vertebral compression fractures, interbody fusion, vertebral disc augmentation or replacement, and other compression fractures including, but not limited to tibial plateau

compression fractures, calcaneous compression fractures, distal tibia fractures, distal radius (wrist) fractures, crushed or fractured orbit and orthopaedic oncology. Further, a minimally invasive distraction and support device would have application in non-orthopaedic surgical procedures in plastic surgery (for example facial reconstruction), gastrointestinal surgery and urological surgery (for example the treatment of incontinence).

One technique used to treat vertebral compression fractures is injection of bone filler into the fractured vertebral body. This procedure is commonly referred to as percutaneous vertebroplasty. Vertebroplasty involves injecting bone filler (for example, bone cement) into the collapsed vertebra to stabilize and strengthen the crushed bone. In this procedure, lower viscosities and higher pressures tend to disperse the bone filler throughout the vertebral body. However, such conditions dramatically increase the risk of bone filler extravasation from the vertebral body.

Kyphoplasty is a modified vertebral fracture treatment that uses one or two balloons, similar to angioplasty balloons, to attempt to reduce the fracture and restore vertebral height prior to injecting the bone filler. Two balloons are typically introduced into the vertebra via bilateral transpedicular cannulae. The balloons are inflated to reduce the fracture. After the balloon(s) is deflated and removed, leaving a relatively empty cavity, bone cement is injected into the vertebra. In theory, inflation of the balloons restores vertebral height. However, it is difficult to consistently attain meaningful height restoration. It appears the inconsistent results are due, in part, to the manner in which the balloon expands in a compressible media and the structural orientation of the trabecular bone within the vertebra.

A tibial plateau fracture is a crushing injury to one or both of the tibial condyles resulting in a depression in the articular surface of the condyle. In conjunction with the compression fracture, there may be a splitting fracture of the tibial plateau. Appropriate treatment for compression fractures depends on the severity of the fracture. Minimally displaced compression fractures may be stabilized in a cast or brace without surgical intervention. More severely displaced compression with or without displacement fractures are treated via open reduction and internal fixation.

Typically, the underside of the compression fracture is accessed either through a window cut (a relatively small resection) into the side of the tibia or by opening or displacing a splitting fracture. A bone elevator is then used to reduce the fracture and align the articular surface of the tibial condyle. A fluoroscope or arthroscope may be used to visualize and confirm the reduction. Bone filler is placed into the cavity under the reduced compression fracture to maintain the reduction. If a window was cut into the side of the tibia, the window is packed with graft material and may be secured with a bone plate. If a splitting fracture was opened to gain access, then the fracture is reduced and may be stabilized with bone screws, bone plate and screws, or a buttress plate and screws. Both of these methods are very invasive and require extensive rehabilitation.

Spinal fusion is most frequently indicated to treat chronic back pain associated with instability or degenerative disc disease that has not responded to less invasive treatments. Fusion is also prescribed to treat trauma and congenital deformities. Spinal fusion involves removal of the spinal disc and fusing or joining the two adjacent vertebrae. The primary objective for patients suffering from instability is to diminish the patient's pain by reducing spinal motion.

Spinal fusions are generally categorized into two large groups: instrumented and non-instrumented. In non-instrumented procedures, the physician removes tissue from the unstable disc space and fills it with some form of bone graft that facilitates the fusion of the two adjacent vertebral bodies. Instrumented procedures are similar to non-instrumented procedures, except that implants (generally metallic) are also applied to further stabilize the vertebrae and improve the likelihood of fusion.

In all interbody surgical approaches, a relatively large opening is made in the annulus. The nuclear material is removed and the end plates are decorticated to facilitate bony fusion. Overall, the use of interbody devices has resulted in mixed clinical outcomes. Placement of a fixed height device presents challenges in proper tensioning of the annulus. For these and other reasons, there is concern over long-term stability of interbody devices and fusion mass.

A need remains for a system and method for distracting or elevating adjacent tissues that is minimally invasive and more easily implemented. Moreover, the system and method should provide a simplified capability for quantifying and controlling the amount of distraction. The system and method should also permit additional augmentation of the distraction site.

SUMMARY OF THE INVENTION

The invention provides a combination of a temporary or long term implantable device and instrumentation to place the device, in which tissue surfaces are distracted along an axis to enable access to the space between the tissues. Generally, the invention provides wafers for stacking upon one another to provide an axially extending column to distract and support tissue surfaces. While a primary use of the invention is to reduce and stabilize vertebral compression fractures, the invention may be used in any situation where it is desirable to distract two tissue surfaces. The tissue may be bone, skin, soft tissue, or combinations thereof. Further, the surfaces may be opposed surfaces of contiguous elements or surfaces of opposed elements. Thus, the invention may be used to treat vertebral compression fractures, for replacement of vertebral discs, as an interbody fusion device, wedge opening high tibial osteotomy, tibial tuberosity elevation, as well as for treating other compression fractures including, but not limited to tibia plateau fractures, calcaneous, distal tibial fractures, or distal radius (wrist) fractures. The invention may also be used for restoring the floor of the orbit, for elevating soft tissue in cosmetic applications, or in incontinence applications as a urethral restrictor. Alternately, the invention may be used in similar veterinary applications.

The terms “vertical”, “up”, etc., are occasionally used herein for ease of understanding, and these terms should be taken in reference to the vertebrae of a standing patient. Thus, “vertical” refers generally to the axis of the spine. We may also utilize mutually perpendicular “X”, “Y” and “Z” axes to describe configurations and movement, with the Z-axis being the axis of the column of wafers, that is, the direction in which this column grows as wafers are added sequentially to it. The X-axis refers to the axis extending generally in the direction of movement of each wafer as it is advanced to a position beneath a preceding wafer, and the Y-axis is perpendicular to both the X- and Z-axes. The wafers are sometimes described with reference to permitted degrees of freedom or restraint when they are placed in a column. It should be understood that these permitted degrees of freedom or restraint refer to the permitted or restrained movement of one wafer with respect to an adjacent wafer along

one or more of the three axes, and the permitted or restrained rotation between adjacent wafers about one or more of these axes.

The distraction device includes a plurality of stackable wafers designed for insertion between tissue surfaces to form a column. The wafer column is assembled *in vivo* to provide a distraction force as well as support and stabilization of the distracted tissue. Preferably, the wafers place distraction force in one direction only and thus provide directional distraction. The distraction device may be permanently implanted, in which case the wafer column may be used alone or in conjunction with a bone filler material. Alternately, the distraction device may be used temporarily to manipulate tissues and then removed.

In use, the wafers are preferably stacked between two tissue surfaces as they are implanted, thereby distracting and supporting the tissue surfaces simultaneously. In the vertebral compression fracture application, it is preferable to distract along the Z-axis (along the axis of the spine) to restore vertebral height. However, in other applications, it may be preferable to provide distraction in a different direction. The features of a wafer and a column of wafers will be described relative to position and direction. The top of a wafer or the top of the column is defined as the face of the wafer or column in the direction of distraction. The bottom of a wafer or the bottom of the column is defined as the face opposite the top face. In similar fashion, above and below a wafer or column implies along the top and bottom of the wafer or column, respectively. Each wafer has a leading edge that enters the forming column first and a trailing edge opposite the leading edge. The sides of the wafer are adjacent the leading and trailing edges and the top and bottom faces of the wafer. In general, the sides are longer than the leading and trailing edges, however the sides may be shorter than the leading and trailing edges. The axis of the column is defined as a line parallel to the direction of distraction.

In order to place the wafers between the tissue surfaces, a wafer insertion apparatus is positioned within the surgical site with access at its distal tip to the tissue surfaces to be distracted and supported. In one embodiment, a wafer is placed on the track and a plunger is used to advance the wafer to the distal end of the track. This is

repeated with consecutive wafers until a column of sufficient height is created per physician discretion. After the wafer(s) have been inserted, the insertion apparatus is removed. The distal end of the insertion apparatus may be manufactured from the same material as the wafers and/or be detachable. In this embodiment, the distal end of the insertion instrument would be detached after placing the wafer column, and the instrument removed.

In another embodiment, the wafer insertion apparatus can be configured for one-hand operation. The wafer insertion apparatus includes an advancement gun assembly that is configured to receive a replaceable wafer cartridge. The cartridge carries a number of wafers to be sequentially inserted into the distraction space by the wafer insertion apparatus. Preferably, the cartridge is biased, meaning that constant pressure is applied to the last wafer of the stack to continually advance wafers to the discharge end of the cartridge. The gun assembly includes a manually operable trigger that operates a linkage mechanism to advance a wafer pusher.

In certain embodiments, the wafer insertion apparatus includes a dual track assembly mounted to the advancement gun assembly. The dual track assembly includes a top track and a bottom track with a wafer "stay" that prevents retrograde motion of a wafer on the way to the distraction site. The top track serves as a carrier for traversing a series of wafers from the cartridge to a delivery or discharge end of the track assembly. The bottom track accepts an individual wafer from the top track at an introduction end of the track assembly and place that wafer in proper position before being advanced or pushed into the distraction site. Wafer stays hold the position of wafers in transit within the track assembly as the pusher and advancing mechanisms are retracted for a subsequent firing.

The wafer insertion apparatus can further include a wafer finger advancer and pusher mechanism. The finger advancer incrementally conveys each wafer one by one with every squeeze of the trigger of the advancement gun assembly. With every stroke of the trigger, the finger advancer advances each wafer within the track assembly incrementally farther down the track to the track tip. In certain embodiments, the finger

advancer can include a series of raised fingers or prongs that engage the bottom rear of each wafer.

The pusher mechanism preferably resides within the bottom track and is configured to push a wafer positioned within the bottom track into the distraction site. The pusher mechanism is also actuated by movement of the trigger of the advancement gun assembly. The pusher is preferably coupled to the finger advancer so that they move in unison.

The top track and bottom track are coupled so that the channels defined by the two tracks intersect adjacent the discharge end of the track assembly. The top track is provided with means for diverting a wafer traveling along the wafer channel of the top track into a pusher channel of the bottom track. In one embodiment, the means for diverting includes a spring finger mounted within the wafer channel and configured to guide a wafer into the pusher channel as it is advanced along the wafer channel.

The present invention provides an apparatus for sequentially inserting wafers into a body space that incrementally advances the wafers to be discharged into the body space. One benefit of the invention is that it prevents retrograde movement of the wafers as they are advanced toward the body space. A further benefit is that the wafers can be provided in a removable and replaceable cartridge without disturbing the apparatus or its engagement with the body space.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a vertebral body having a compression fracture displacing its superior and anterior edge.

FIG. 2 shows a vertebral body, following treatment of a compression fracture.

FIG. 3 illustrates a plan view of a distraction device insertion apparatus according to an embodiment of the invention, placed within a vertebral body shown in cross-section.

FIG. 4 shows a plan view of a further configuration of distraction device being deployed within a vertebral body, shown in sectional view.

FIG. 5 illustrates a cross-sectional view of the insertion apparatus of **FIG. 3** deploying a distraction device according to an embodiment of the present invention.

FIG. 6 shows a sectional view of an insertion apparatus according to one embodiment of the present invention.

FIG. 7 is a perspective, partially exploded view of a wafer insertion apparatus in accordance with a further embodiment of the invention.

FIG. 8 is an exploded view of the advancement gun component of the wafer insertion apparatus shown in **FIG. 7**.

FIG. 8 is an exploded view of the wafer cartridge component of the wafer insertion apparatus shown in **FIG. 7**

FIG. 10 is an enlarged view of the interface between the wafer cartridge component shown in **FIG. 9** and a cartridge latch component of the wafer insertion apparatus shown in **FIGS. 7** and **8**.

FIG. 11 is an enlarged side cut-away view of the wafer insertion apparatus shown in **FIG. 7**.

FIG. 12 is an enlarged perspective view of the trigger and advancer carriage components of the advancement gun shown in **FIG. 8**.

FIG. 13 is an exploded view of the track assembly component of the wafer insertion apparatus shown in **FIG. 7**.

FIG. 14 is an exploded view of an advancer/pusher assembly for use with the wafer insertion apparatus shown in **FIG. 7**.

FIGS. 15(a)-**15**(c) are side partial views of the advancer/pusher shown in **FIG. 14** mounted within the track assembly shown in **FIG. 13** in different stages of operation to advance a wafer along the track assembly.

FIGS. 16(a)-(c) are side views of the apparatus depicting various stages of advancement of a wafer to the discharge end.

FIG. 17 is perspective cut-away view of a wafer insertion apparatus according to a further embodiment of the invention..

FIG. 18 is a side cross-sectional view of the wafer cartridge portion of the apparatus shown in **FIG. 17**.

FIG. 19 is a perspective cut-away view of a wafer insertion apparatus according to a further embodiment of the invention.

FIG. 20 is a side partial cross-sectional view of a wafer insertion apparatus with a modified wafer cartridge according to an additional embodiment of the invention.

FIG. 21 is an enlarged view of a portion of the apparatus shown in **FIG. 20**.

FIG. 22 is an enlarged perspective view of the discharge end of the apparatus shown in **FIG. 7**

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and described in the following written specification. It is understood that no limitation to the scope of the invention is thereby intended. It is further understood that the present invention includes any alterations and modifications to the illustrated embodiments and includes further applications of the principles of the invention as would normally occur to one skilled in the art to which this invention pertains.

The invention provides a combination of an implantable distraction device and instrumentation to place the device. The distraction device is detailed in this section by its application to the vertebral compression fracture. **FIG. 1** shows a vertebral body **10** having a compression fracture displacing its superior and anterior edge **11**. **FIG. 2** shows a vertebral body **10** wherein the height has been restored.

In accordance with the present invention, a plurality of stackable wafers can be provided for insertion between two tissues and can be delivered to a surgical site along an axis transverse to the axis of distraction. Multiple wafer insertions result in a column of wafers at the surgical site that simultaneously distracts and supports the two tissues.

The wafers may be formed from a solid form of bone filler material, and/or any other suitable material such as, but not limited to, implantable grade alloys, medical grade composites, medical grade polymers, ceramics, hydrogels and resorbable polymers. The wafers may be dense or porous, while porous wafers may be filled with resorbable polymers, drug therapies or osteoinductive agents.

The present invention provides that the wafer column is formed *in vivo* by using a wafer insertion apparatus. **FIG. 3** illustrates the distal or discharge end portion **16** of a wafer insertion apparatus **15** placed within a vertebral body **10** with a wafer **18** positioned distally on the wafer insertion apparatus **15**. During implantation, a plurality of such wafers **18** are stacked to form a column to restore vertebral height, such as the column **20** depicted in **FIG. 5**.

Consecutive wafer insertions result in a column of wafers at the surgical site. In one embodiment, the trailing edge of a wafer can be beveled or otherwise configured to

guide the next wafer under the first. For instance, the wafer **22**, depicted in **FIG. 5**, includes a beveled leading edge **23**. This beveled edge **23** facilitates guiding the wafer under the trailing edge **24** of a preceding wafer **22**. The trailing edge is correspondingly beveled to guide the subsequent wafer underneath.

The wafers **22** can have a variety of configurations and dimensions depending upon the particular surgical application. For instance, for vertebral compression fracture applications, exemplary wafer dimensions range as follows:

- Wafer length between 5 mm and 50 mm;
- Wafer width between 2 mm and 16 mm;
- Wafer thickness between 0.2 mm and 6 mm; and
- Curved wafer radii between 10 mm and 500 mm.

These dimensions are provided only as guidelines and any suitable dimensions may be used. Furthermore, the dimensions of the wafer will likely vary widely when the wafers are used in other applications, such as, for example, treating tibial plateau fractures.

In certain applications, it may be beneficial for the wafers to be secured to one another after insertion. Any suitable method for securing the wafers to one another as known by those skilled in the arts may be used. Wafers may be secured to one another by means of an adhesive bond, a chemical bond, and/or a mechanical interlock (as described above). Applying a generic fluent adhesive, for example cyanoacrylate, into the cavity surrounding the column provides adhesive bonding. The fluent adhesive hardens and locks the wafers.

The wafers may also include tunnels, grooves, or holes to facilitate movement of bone filler or other fluent materials through the wafer column into the surrounding bone. Further, openings may be provided through the wafers to allow communication between the tunnels, grooves, or holes or adjacent wafers. In any configuration, bone filler material injected into the wafer column would then flow through the column, fully encapsulating the wafers and better bonding the wafers to the bone filler. Further details of suitable wafers are disclosed in U.S. Patent No. 6,595,998 (the '998 Patent), entitled "Tissue Distraction Device", which issued on July 22, 2003, to the assignee of

the present invention. The disclosure of this '998 Patent is incorporated herein by reference.

In a clinical application, the wafers are inserted such that consecutive wafer insertions form a column **20**, as shown in **FIG. 5**. The wafers in the column can be equally sized wafers, such as the intermediate wafers **26**. Alternatively or in addition, the column can include larger top and bottom wafers **27**, **28**, respectively, to provide a larger surface area over which to distribute loads. Moreover, the larger wafers create a space or channel **30** between the edges of the intermediate wafers **26** and the surrounding tissue. This channel provides a path around the interspaced wafers through which a bone filler or other fluent material may flow to fully encapsulate the wafers and to interdigitate with surrounding tissue.

A wafer insertion apparatus is provided as part of the invention to deliver the wafers to the surgical site and to form a column of wafers. In one embodiment, the wafer insertion apparatus applies a force along the X-axis (the axis of insertion) to a wafer that is to be added to the column. As previously described, the wafers may be configured with beveled ends to facilitate growth of the column along the Z-axis (the vertical axis through the wafers) as the additional wafer is inserted.

Numerous variations of the wafer insertion apparatus are possible, the embodiments generally including, but not limited to, a track, a plunger, and a cartridge. The wafer insertion apparatus is comprised of a track, which is a long narrow channel through which wafers pass when placed into the wafer column. A plunger generally advances wafers down the track. Multiple wafers can be housed in a cartridge of the wafer insertion apparatus for advancement down the track. Preferably included is a mechanism for feeding subsequent wafers into the track in front of the plunger. Further, the track is configured for removal from the surgical site while leaving the wafer column intact.

One embodiment of a wafer insertion apparatus **35** described in the '998 Patent is illustrated in **FIG. 6**. The handle **36** may be gripped to position the wafer insertion apparatus **35**. The wafer insertion apparatus has, at its proximal end **38**, a magazine **40** containing wafers **41**. The wafers **41** may be stacked in the magazine **40** with a top

surface of one wafer supporting the bottom surface of an adjacent wafer. The handle **36** is equipped with a trigger **37** for forcing wafers out of the magazine **40**. Optionally, the magazine **40** is equipped with a spring **43** to load wafers **41** along a track **45** of the inserter **35**. The track **45** extends from the magazine **40** to the surgical site at its distal end **46**. As they enter the wafer track **45**, the wafers **41** are aligned with the leading edge of one wafer adjacent the trailing edge of a preceding wafer. The track **45** in the wafer insert **35** shown in **FIG. 6** includes a lower cavity **48** and an upper cavity **49**. A plunger **51** extends through the lower cavity **48** while the wafers **41** are aligned along the upper surface of the plunger. An opening is provided along the top surface of the lower cavity **48** at the distal end **46** of the track **45** to accommodate a wafer. Thus, as the plunger is retracted past the trailing edge of the furthest distal wafer, the wafer drops into the lower cavity. The plunger pushes the wafer distally to form a column of wafers **53**.

In one embodiment of the invention, a wafer insertion apparatus **60** includes a wafer cartridge **61**, a track assembly **63** and an advancement gun **65**, as shown in **FIG. 7**. Referring to the exploded view in **FIG. 8**, the advancement gun **65** includes left and right housings **67**, **68** that can be coupled together in a known manner. Preferably, the housings are formed of a high-density plastic material that can be molded to define various interior and exterior features. The housings support a manual trigger **70** that is pivotably mounted to the housings **67**, **68** by a pivot pin **71**. The trigger **70** includes a manual grip **72** that is accessible outside the housings, and a lever arm **73** that operates within the housing. The lever arm **73** includes a return spring tab **74**, seen best in **FIG. 11**, which provides a connection point for a return spring **76**. The return spring **76** can be mounted within the handle **78** to apply a restorative force to the trigger **70** after it has been manually depressed and released.

The advancement gun **65** includes a wafer advancement carriage **80** that is slidably disposed within an advancer channel **90** in the housings **67**, **68**, as shown in **FIG. 11**. The carriage **80** is connected to the lever arm **73** of the trigger **70** by way of a link **82**. The link **82** is pivotably connected to the lever arm **73** and the carriage **80** by corresponding pivot pins **84**, as depicted in **FIGS. 11** and **12**. As can be discerned from **FIG. 11**, when the trigger **70** is depressed, the lever arm **73** pivots in a clockwise

direction, which pushes the link **82** against the carriage **80**. Since the carriage is constrained within the channel **90**, the pivoting movement of the trigger is translated to a linear movement of the carriage **80** toward the distal end **69** of the advancement gun **65**. Each depression of the trigger constitutes one cycle of operation of the advancement gun, which corresponds to moving each wafer an incremental distance toward the discharge end **64** of the track assembly **63**. This incremental distance is determined by the "throw" of the advancement gun, which in turn is related to the angle through which the trigger **70** can pivot within the gun. In the preferred embodiment, the throw of the advancement gun corresponds to a distance slightly greater than the length of a wafer.

The advancement gun **65** includes means for engaging a removable wafer cartridge, such as the cartridge **61**. This feature allows a cartridge to be replaced while the apparatus is still in its operative position relative to the tissue surfaces being distracted. The distal end **69** of the advancement gun **65** defines engagement slots **95** that interface with locking cams **102** on opposite sides of the cartridge housing **100** (see **FIG. 9**). The cams **102** are configured to slide into the engagement slots **95**. The advancement gun **65** includes latch halves **97** pivotably mounted to corresponding housing halves **67**, **68** by a pivot pin **98** passing through a bore **99**. The ends **96** of the latch halves **97** are turned inward to engage an end face **102a** (**FIG. 7**) of the locking cams **102** on cartridge **61**. When the latch ends engage the end face of the cartridge, they push the locking cams **102** into the slots **95**. The latch halves can be provided with finger tabs **97a** that can be pushed or pulled to engage or release the cartridge engagement means.

Referring again to **FIG. 9**, the cartridge **80** is shown with a housing **100** defining a cavity for receiving a stack of wafers **101**. The cartridge can be provided pre-loaded so that the cartridge can be simply engaged to the advancement gun **65**, and then removed and replaced once all the wafers have been discharged. The cartridge **61** can include a removable retainer clip **107** that spans the cavity in the housing **100** to hold the wafer stack **101** within the cartridge until it is needed. The arms of the clip **107** pass through openings **108** in the cartridge and underneath the stack **101**. The retainer clip

is kept in place as the cartridge is loaded in the advancement gun and then removed so that the stack **101** moves vertically into the gun.

In one embodiment, the cartridge **61** includes a spring plate **104** that is mounted on top of the stack **101**. A spring arrangement (not shown) can be disposed between the spring plate **104** and the top of the housing **100** to provide pressure on the stack **101**. The spring plate **104** can include a number of posts **105** configured to support the spring arrangement. The spring arrangement thus ensures that the lowermost wafer of the stack **101** is situated at the base of the cartridge during operation of the apparatus **60**.

Turning back to **FIGS. 8** and **11**, the wafer advancement carriage **80** includes an advancer attachment notch **86** at its distal operating end. An attachment post **87** encroaches into the notch **86**, as best seen in **FIG. 12**. The notch **86** and post **87** are provided for attaching an advancer or pusher **135** shown in **FIG. 14**. The pusher **135** includes an opening **139** at its proximal or engagement end **138**. The engagement end **138** is configured to slide into the notch **86** of the carriage until the post **87** engages the opening **139** to lock the pusher **135** to the carriage **80**.

As also shown in **FIGS. 8** and **12**, the carriage **80** includes an upper ratchet face **109**. This ratchet face **109** engages a full throw assembly **110** that is configured to ensure that the carriage **80** travels through its full stroke before being allowed to return to its starting position (such as by operation of the return spring **76** connected to the trigger **70**). The full throw assembly **110** includes a ratchet clip **111** that engages the ratchet face **109** of the carriage as the carriage is advanced toward the distal end **69** of the advancement gun. Thus, as long as the ratchet face **109** is in contact with the clip **111**, the carriage cannot move on its return stroke. Once the carriage has been advanced far enough toward the distal end **69** so that the ratchet face **109** is clear of the clip, the carriage can be drawn back to its initial position by the lever arm **73** and link **82**, preferably by operation of the spring **76**. This feature ensures that the trigger will be fully depressed and a wafer advanced through a full cycle of movement. Absent this feature, a partial depression of the trigger could cause the wafer insertion apparatus to

jam as a partially advanced or partially loaded wafer gets lodged within the track assembly **63**.

Details of the track assembly **63** can be seen in **FIG. 13**. In the preferred embodiment, the track assembly **63** includes a top track **115**, a bottom track **120** and a wafer stay **125**. The track assembly **63** is mounted to the wafer cartridge **100**, which is mounted to the distal end **69** of the advancement gun **65**. In one embodiment, the end walls **61a** of the wafer cartridge housing **100** define a slot **103** into which the track assembly **63** is mounted. The top track includes a wafer insertion opening **116** that is disposed immediately beneath the wafer stack **101** when the track assembly is mounted within the slot **103**. The top track further defines a wafer channel **117** along its length that provides the initial path along which a succession of wafers can be advanced to the discharge end **64** (**FIG. 7**) of the apparatus. The end **118** of the top track is configured to engage the bottom track at a location **121**. Preferably, the end **118** is configured to wrap around the bottom track at this location and can be suitably affixed so that the track assembly **63** is substantially rigid.

The channel **117** of the top track **115** retains the wafer stay **125**, which functions to hold wafers within the channel **117** as the advancer/pusher mechanism **92** follows its return stroke (as explained below). A tab **127** at the proximal end of the wafer stay engages the distal end of the wafer insertion opening **116** to hold the stay in place. The wafer stay **125** includes a series of substantially evenly spaced intermediate prongs **126**. The prongs **126** project downward at an angle into the wafer channel **117**, facing the discharge end **64**, as illustrated in **FIG. 15(a)**. With this orientation, the prongs **125** do not impede forward movement of wafers along the channel. However, the prongs prevent retrograde movement since the free end of the prongs contact the back end of a wafer as it moves backward in the channel. Preferably, prongs **126** of the wafer stay **125** are formed of a material that is sufficiently firm to resist this retrograde movement, yet sufficiently flexible to deflect upward as a wafer passes underneath. For example, the prongs, as well as the entire wafer stay, may be formed of a thin gage stainless steel.

Again referring to **FIG. 13**, the bottom track **120** defines a pusher channel **124** that receives the advancer/pusher mechanism **92** (**FIGS. 7** and **14**) for reciprocating linear motion. The top track **115** is configured to overlie the bottom track **120** and engages the bottom track at the engagement end **118**, as described above. It should be noted that the engagement end **118** is configured to provide an exit opening for a wafer that has traveled the length of the top track. The wafer thus exits the top track and drops into the bottom track **120** at the introduction slot **121**.

In one aspect of the invention, the wafer stay **125** is configured to assist in this track change. In particular, in a preferred embodiment, the distal end of the wafer stay includes a pair of opposite spaced apart leaf springs **128**. These leaf springs help maintain the wafer stay **125** within the top track **115** and also help keep the wafers in a proper orientation for entry into the introduction opening **121** of the bottom track, as best illustrated in **FIG. 15(c)**. The wafer stay **125** also includes a dislodgement leaf spring **129** that is angled downward toward the bottom track. As a wafer moves toward the discharge/engagement end **118**, the dislodgement leaf spring **129** pushes the wafer down into the introduction opening **121** of the bottom track **120**. Once the wafer is within the bottom track, the pusher (**FIG. 14**) can be used to advance the wafer to the wafer discharge opening **122** of the bottom track **120**. As explained above, this discharge opening is situated within the body space to be distracted.

Details of the advancer/pusher mechanism **92** can be seen in **FIG. 14**. The mechanism includes an advancer **131** that includes a series of substantially evenly spaced fingers **132**. These fingers project upward into the top track **115** when the advancer/pusher mechanism is disposed within the channel **124** in the bottom track **120**, as shown in **FIG. 15(b)**. Like the wafer stay **125**, the fingers **132** on the inserter **131** are angled forward. This forward sweep of the fingers allows the inserter **131** to be retracted without pulling a wafer backward with it. As with the wafer stay, the fingers **132** are preferably spaced apart a distance slightly greater than the length of a wafer. In this way, the length of the tracks can be minimized and the regularity of the wafer insertion can be maintained.

The advancer **131** includes attachment clips **133** that engage attachment slots **137** in the pusher **135**. Thus, the advancer **131** and pusher **135** are coupled and move together within the channel **124** of the bottom track. However, unlike the advancer, the pusher **135** essentially only operates on a wafer that is within the discharge opening **122** of the bottom channel. Thus, the pusher **135** includes a pusher end **136** that is configured to engage the proximal end of a wafer. The opposite end of the pusher defines an engagement end **138** and opening **139** that engage the wafer advancement carriage **80** as described above.

The operation of the track assembly **63** and advancer/pusher mechanism **92** can be understood from consideration of **FIGS. 15(a)-(c)**. In **FIG. 15(a)**, a wafer **22** is shown within the wafer channel **117** of the top track **115**. The wafer includes a leading beveled end **23** that facilitates introduction of the wafer **22** underneath a previously advanced wafer disposed at the distraction site. The proximal end of the wafer preferably defines an advancement notch **140** that can be engaged by the wafer advancer **131** and the pusher **135**. As shown in **FIGS. 15(a)-(b)**, a finger **132** of the advancer **131** engages the notch **23** of the wafer **22** to push it along the top track **115** toward the distraction site. A prong **126** of the wafer stay **125** is also shown in **FIG. 15**(a), wherein the prong is deflected upward to allow passage of the wafer.

In one embodiment of the invention, the wafer **22** can be provided with a notch **142** at its leading end. Prongs **126** of the wafer stay **125** can resiliently drop into the notch **142** as the leading end of the wafer advances to prevent retrograde movement of the wafer. In the illustrated embodiment of **FIG. 13**, the wafer stay includes four prongs **126** to engage the notch **142** of three wafers situated within the wafer channel **117**. In the illustrated embodiment, the prongs **126** are spaced along the top track by a distance slightly greater than the length of a wafer. Alternatively, a greater number of prongs can be provided, with the understanding that when the wafers sit within the wafer channel at the end of a stroke some prongs will engage the retrograde notches **142** of the wafers while other prongs will be resiliently compressed by the wafers.

As the wafer moves toward the engagement end **118** of the top track, the dislodgement leaf spring **129** of the wafer stay **125** contacts the wafer, as shown in **FIG.**

15(c). The spring **129** pushes the wafer downward into the bottom track **120**. It can be seen in **FIG. 15(c)** that the pusher **135** is beneath the wafer. Once the wafer is disposed within the introduction opening **121** of the bottom track **570**, the end **136** of the pusher can then contact the advancement notch **23** of the wafer. The advancer/pusher mechanism **92** is propelled toward the discharge end **64** of the apparatus, so the pusher end **136** continues to push the wafer until it is firmly positioned at the bottom of the distraction stack.

As should be apparent, the advancer/pusher mechanism **92** (including the connected advancer **131** and pusher **135**) moves in the pusher channel **124** of the bottom track **120** relative to the stationary wafer stay **125**, which is fixed within the wafer channel **117** of the top track **115**. Thus, as the advancer/pusher mechanism **92** is retracted, the fingers **132** of the wafer advancer **131** slide along the bottom of the wafers remaining in the wafer channel **117** until the wafer advancement carriage **80** reaches the end of its return stroke. At this point, the rearmost prong **132a** is situated beneath the wafer cartridge **61**. A wafer from the stack **101** that has fallen into the opening **116** in the top track **115** is engaged by the finger **132a**. When the trigger **70** is depressed again, the carriage **80** propels the advancer/pusher mechanism **92** to simultaneously propel one wafer into the wafer discharge opening **122** of the bottom track **120** and other wafers within the top track along the wafer channel **117**. This procedure is repeated until the stack of wafers has been fully formed within the distracted body.

A sequence of events in the use of the insertion apparatus **60** is depicted in **FIGS. 16(a)-(c)**. When the apparatus **60** is initially actuated, a wafer **22** is situated at the bottom of the wafer stack **101** within the wafer channel **117**, as shown in **FIG. 16(a)**. The advancement notch **140** of the wafer is engaged by a finger **132** of the wafer advancer **131**. The remainder of the wafer channel **117** is empty. As the wafer advancement carriage **80** is translated forward (by depressing the trigger **70** of the advancement gun **65**), the carriage pushes the wafer advancer **131**, and ultimately the finger **132** advances the wafer along the top track **115**, as shown in **FIG. 16(b)**.

The wafer advancer **131** is shown near the end of its stroke in **FIG. 16(b)**. When the advancer has been fully advanced, the wafer **122** is caught by the first prong **126** of the wafer stay **125**. The advancer is then retracted with the carriage **80** until the advancer **131** is aligned under the wafer stack **101**, as depicted in **FIG. 16(a)**. The next wafer has already dropped through the opening **116** in the top track **115** and is awaiting engagement by the finger **132**. The above steps are repeated and with each successive depression of the trigger the wafers **22** advance to the next prong **126** of the wafer stay.

On the fourth actuation of the advancement gun **65**, the initial wafer **22** is in the position shown in **FIG. 16(c)**. As explained above, the dislodgement prong **129** directs the wafer from the wafer channel **117** in the top track **115** to the pusher channel **124** in the bottom track **120**. As the pusher **135** is retracted, the wafer is held in place within the wafer introduction slot **121**. When the advancer/pusher mechanism **92** is fully retracted, the pusher **135** engages the advancement notch **140** in the lead wafer . Subsequent activation of the gun **65** causes the pusher **135** to propel the wafer into the discharge opening **122**.

In the embodiment illustrated in **FIGS. 7-16**, the wafers are introduced into the body cavity from the bottom of the wafer stack. In other words, with this embodiment, each successive wafer pushes the previously stacked wafers upward to distract the space. In an alternative embodiment, the wafers are stacked in the opposite direction. Thus, a wafer insertion apparatus **150** shown in **FIGS. 17-18** includes an advancement gun **152** and a wafer cartridge supported on the underside of the gun. The track assembly **156** is supported by the gun. The gun includes a trigger **158** that reciprocates a wafer advancement carriage **160** engaged to an advancement/pusher mechanism **162**. All of these components can be configured similar to the prior embodiments, except that they are modified to advance each wafer onto the top of the stack within the body cavity.

The track assembly **156** includes a top track **164** and a bottom track **166** that are essentially the analog of the bottom track **120** and top track **115**, respectively, of the previous embodiment. Thus, each wafer exits the apparatus **150** from a discharge

opening **167** in the bottom track **166**. The moving components of the apparatus **150** can be configured similar to the like components of the previous embodiment, except that components of the apparatus **150** of **FIGS. 17-18** are switched between the top and bottom tracks from those in the apparatus **60**.

As shown in **FIG. 18**, the wafer cartridge **154** is mounted to the underside of the advancement gun **152**. Thus, each wafer is fed upward into the bottom track **166** and into engagement with the advancement/pusher mechanism **162**. In order to drive the stack into the advancement mechanism, a spring plate **169** is biased upward into the wafer stack by an arrangement of springs **170**. This arrangement is similar to the spring biased stack described above in connection with the apparatus **60**.

The present invention contemplates a trigger driven advancement/pusher mechanism, such as the mechanism **92** described above. In the previous embodiments, the trigger, such as trigger **70**, is connected to a carriage **80** by a floating link **82**. Other trigger or actuation mechanisms are contemplated by the invention. For example, in one alternative embodiment, a wafer insertion apparatus **175** includes an advancement gun **176**, a bottom loaded cartridge **177** and a track assembly **178**, as shown in **FIG. 19**. An advancement/pusher mechanism **180** is engaged to a carriage **181** that is slidably disposed in the gun, in a fashion similar to the embodiments described above.

The gun further includes a trigger **184** that is pivotably engaged to the gun at a pivot mount **185**. In this embodiment, the carriage **181** includes a rack gear **182** facing the trigger. The trigger **184** includes a clock gear **186** that meshes with the rack gear **182** as the trigger is pivoted. Thus, the drive interface between the trigger and the carriage is direct, without any intermediate linkage structure.

In a further aspect of this embodiment, the trigger **184** defines a stop face **188**. This stop face contacts a stop wall **189** of the advancement gun **176** to prevent further pivoting of the trigger. More significantly, when the trigger can no longer pivot, the translation of the carriage **181** stops, signifying the end of the stroke of the advancement/pusher mechanism **180**. With this feature, the full throw assembly **110**

(**FIG. 8**) can be eliminated. Similarly, the back face **190** of the trigger **184** can contact a rear stop wall **191** to limit the return movement of the trigger, and therefore the carriage.

In the embodiments disclosed above, the wafer cartridge is oriented to form a vertical stack of new wafers to be introduced into the body cavity. In an alternative embodiment, the wafer cartridge can provide the wafers in a horizontal arrangement, as depicted in **FIG. 20**. In this embodiment, the top track is essentially replaced by a cartridge **190** that is mounted on the single track **195**. The wafers **22** are provided in a row within the wafer channel **191** of the cartridge, essentially spanning the length of the track **195**. The wafer channel is provided with an opening **192** that mates with a wafer introduction slot **197** in the track **195**. A deflection prong **193** is mounted within the channel and performs essentially the same function as the dislodgement spring **129** of the previous embodiments – i.e., to direct the leading wafer into the track **195**.

In this embodiment, a wafer advancer **205** is disposed in the wafer channel **201** of the cartridge. Fingers **206** on the wafer advancer engage the back end of the wafers to push the wafers along the channel as the advancer is reciprocated. As with the wafer advancer **131**, the fingers **206** can be flexible to retract as the advancer is withdrawn from the end of its stroke.

In order to maintain the position of the wafers **22** during the return stroke of the advancer **205**, the cartridge **190** can be provided with spring fingers **215** on opposite sides of the channel **191**, as shown in **FIG. 21**. The fingers **215** are arranged at an angle toward the direction of travel of the wafers so that they retract as a wafer passes. However, retrograde movement of the wafers causes them to contact the spring fingers **215** and push them into the middle of the channel **191**, thereby preventing further retrograde travel of the wafers.

Returning to **FIG. 20**, the apparatus also includes a pusher **210** disposed in the pusher channel **196** of the track **195**. Unlike the prior embodiments, the pusher **210** is separate from the wafer advancer **205**. The pusher **210** and the advancer **205** can be engaged to posts **201** on a modified carriage **200**. The carriage can be driven in any of the manners described above. It can be appreciated that when the carriage **200** translates it propels the wafer advancer **205** and pusher **210** toward the discharge end

198. The wafers are advanced and discharged in substantially the same manner as the embodiments described above.

In a further feature of the invention, the apparatus can be provided with means for interfacing with a vertebral body to help stabilize the apparatus. In particular, the bottom track **120** of the assembly **61** illustrated in **FIG. 7** can be configured to mate with features formed in the cortical bone of a vertebral body. As shown in **FIG. 22**, the apparatus **61** is introduced into an opening **O** in a vertebral body **10**. In this instance, as discussed in the '998 Patent incorporated by reference, the wafers are used to distract and restore the height **h** of a vertebral body **10** (see **FIG. 2**). The opening **O** thus provides access to the cancellous bone of the vertebral body. The opening **O** can be prepared using a bone working tool such as a drill. In order to help guide the wafer insertion apparatus **61**, the base of the opening can be formed with a step **S**. The step is configured to be engaged by a slot **225** in the discharge opening **122** of the bottom track **120**. With the slot **225** engaging the step **S** the discharge end of the apparatus is stabilized as the wafers are introduced.

While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptation and modification may be made therein without departing from the spirit of the invention and the scope of the appended claims.